UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,968	03/10/2004	Kent A. Louviere	298.032	9019

29166 7590 03/23/2005

DOMINGUE & WADDELL, PLC
P.O. Box 3405
LAFAYETTE, LA 70502

EXAMINER	
STAICOVICI, STEFAN	

ART UNIT	PAPER NUMBER
1732	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,968	LOUVIERE, KENT A.	
	Examiner	Art Unit	
	Stefan Staicovici	1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because the abstract should be a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. It is suggested to include a description of a method of making a plurality of interconnected vials. Correction is required. See MPEP § 608.01(b).

2. The disclosure is objected to because of the following informalities:

- in paragraph [0030], line 1, "FIG 2" should be replaced with --FIG 2A and 2B--;

Appropriate correction is required.

Drawings

3. The drawings are objected to because the label "Figure 2" should be deleted since the original specifications refers only to Figures 2A and 2B. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 20 and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,101,791 in view of Porfano *et al.* (US Patent No. 6,164,044).

U.S. Patent No. 6,101,791 teaches the basic claimed process for manufacturing a plurality of interconnected vials including, providing a mold having a first member having a first end with an opening defined within said first end and, a second end; a manifold member operatively attached to said second end of said first member for channeling a plastic fluid to a first slide and a second slide positioned within the opening, with said first slide and second slide having an extended position and a contracted position, and a means for extending said first slide and said second slide to the extended position; a second member having a first end and a second end, and wherein said first end of said second member contains a plurality of core pins contained therein; an ejector plate selectively attachable to said second member, said plurality of core pins being disposed therethrough; and, a piston adapted to said second end of said second member for reciprocating said second member into engagement with said first slide and said second slide. Further, U.S. Patent No. 6,101,791 teaches heating a plastic so that the plastic fluid is formed, channeling the plastic fluid into the manifold, heating the plastic fluid within said manifold, injecting the plastic fluid through said first member and into said first slide and said second

slide, moving said piston so that said second member contacts said first slide and said second slide, contracting said first slide and said second slide so that said contracted first slide and said second slide form a plurality of cavity profiles and wherein said plurality of cavities are linked together by a plurality of arms, said cavity profiles having a first end and a second end, with the first end containing a wing tip contour, and the second end being opened, placing said plurality of core pins into said plurality of cavity profiles and wherein said plurality of core pins are in a free standing arrangement within said cavity profiles, injecting the plastic fluid into said cavity profiles, injecting the plastic fluid about said plurality of core pins so that the plasticized fluid is disposed about said core pin so that the plurality of interconnected medical vials are formed, reciprocating the piston away from the first end of said first member, allowing the first slide and second slide to expand, reciprocating the piston so that the ejector plate axially traverses the plurality of core pins, ejecting the plurality of interconnected medical vials from the plurality of core pins and wherein said plurality of interconnected medical vials contains a winged tip extension on the first end and a cylindrical outer diameter on the second end. Furthermore, U.S. Patent No. 6,101,791 teaches providing a drug in a liquid embodiment, inserting the liquid into the open end of said molded plurality of interconnected medical vials, heat sealing the open end so that the plurality of interconnected medical vials are a plurality of closed (encapsulated) containers.

Regarding claims 20 and 26, US Patent No. 6,101,791 does not teach placing said interconnected vials within a vial holder tray. Porfano *et al.* ('044) teach a process for assembling and packaging a plurality of medical plastic vials (col. 4, lines 50-60) including,

positioning said vials prior to packaging in a tray (84) (see Figure 5). Therefore, it would have been obvious for one of ordinary skill to have provided a tray as taught by Porfano *et al.* ('044) to hold a plurality of interconnected vials in the process of US Patent No. 6,101,791 because, Porfano *et al.* ('044) specifically teach the use of a tray for holding a plurality of plastic vials prior to packaging and sealing said vials whereas, US Patent No. 6,101,791 teach molding and ejecting a plurality of plastic medical vials and further, filling and sealing said molded plastic medical vials and also because, both references teach similar materials and end-products.

6. Claims 20-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,735,927 B1.

Claims 1-17 of U.S. Patent No. 6,735,927 B1 teach the basic claimed process of manufacturing a plurality of encapsulated interconnected vials with a mold having a first member having attached thereto a plurality of core pins including, forming a plurality of cavity profiles linked together by a plurality of arms by contracting a first slide and a second slide from an extended position to a contracted position; inserting the plurality of core pins on said first member into said plurality of cavity profiles so that said plurality of core pins are free standing; injecting a plastic fluid about said plurality of core pins to form a plurality of interconnected vials; removing the plurality of interconnected vials from the mold; positioning the plurality of interconnected vials into a holder tray; placing a liquid into the plurality of interconnected vials; heat sealing an open end of the plurality of interconnected vials so that each of the plurality of interconnected vials forms a closed container that encapsulates the liquid, and wherein the step of heat sealing includes, clamping the plurality of interconnected vials into a heat sealing device;

applying heat to the heat sealing device; measuring the temperature of the applied heat; measuring the time heat is applied to said heat sealing device. Further, Claims 1-17 of U.S. Patent No. 6,735,927 B1 teach terminating the heat applied to a first arm of said heating sealing device after a predetermined time; unclasping the first arm from a second arm of said heating sealing device; removing the plurality of interconnected vials from said holder. Furthermore, Claims 1-17 of U.S. Patent No. 6,735,927 B1 teach that the liquid comprises a medicine and wherein the step of placing the liquid into the plurality of interconnected vials includes measuring a predetermined amount of medicine and injecting the predetermined amount of the medicine into the plurality of interconnected vials. It is noted that all the limitations of claims 20-30 are "fully encompassing" of claims 1-17 of U.S. Patent No. 6,735,927 B1 and as such a secondary reference is not required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 20-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright *et al.* (US Patent No. 5,736,173) in view of Beck *et al.* (US Patent No. 5,040,963) and in further view of Porfano *et al.* (US Patent No. 6,164,044), McGahhey (US Patent No. 6,336,489) and JP 11-100008.

Wright *et al.* ('173) teach the basic claimed process of injection molding a container with an open end and a closed end, including a mold (10), said mold (10) having a first member (40, 34) including a female mold (14) (insert), neck ring (16), slide taper blocks (38a, 38b) and slides (36a, 36b). Further, Wright *et al.* ('173) teach a second member having a core (12) and a sleeve (30) that abuts against slides (36a, 36b) in order to further position neck ring (16), hence forming mold cavity (18) therebetween. As shown in Figure 1the outer surface (36c) of each slide includes an inclined portion (36d), which permits motion of the sliders between an extended position and a contracted position. The injection molding process of Wright *et al.*('173) includes heating plastic material to form a stream of molten plastic material, positioning core (12) to form mold cavity (18) by contacting sleeve (30) against slides (36a, 36b), slider taper blocks (38a, 38b) and neck ring (16) in order to further position neck ring (16), hence forming mold cavity (18) therebetween, injecting molten plastic into mold cavity (18) through nozzle (20), in order to form a tubular product having an open end and a closed end (container).

Regarding claims 20 and 26, Wright *et al.* ('173) do not teach a plurality of cores and a manifold member attached to first member. Beck *et al.* ('963) teach an injection molding apparatus having a manifold for injection molding a plurality of containers. As seen in Figure 1 of Beck *et al.* ('963) a manifold system for a multicavity molding system includes a plurality of

molding cavities (3), a plurality of cores (5) and a plurality of hot runners (33,35, 37) The molten material is channeled and injected into manifold (19) via valves (21,23) and hot runners (33, 35, 37). Heating means (39) is provided to maintain and control the temperature of the molten material as it is distributed through the hot runners of the manifold system. It would have been obvious for one of ordinary skill in the art at the time of the invention to use a plurality of molding cavities and cores, and the manifold system of Beck *et al.* ('963) in the process of Wright *et al.*('173) in order to increase productivity by increasing the number of components manufactured in one production cycle and to improve process control by maintaining the temperature of the molten material at a constant temperature, hence avoiding short shots.

Further regarding claims 20 and 26 and in regard to claims 21–25 and 27-30, Wright *et al.*('173) in view of Beck *et al.* ('963) do not teach a process for sealing said molded containers (vials). Porfano *et al.* ('044) teach a process for assembling (measuring) and packaging a plurality of medical plastic vials (col. 4, lines 50-60) including, positioning said vials prior to packaging in a tray (84) (see Figure 5), filling (measuring) said vials with a liquid (medicine) and sealing said vials (see col. 10, lines 35-40). Therefore, it would have been obvious for one of ordinary skill in the art to have filled said vials with a liquid as taught by Porfano *et al.* ('044) in the process of Wright *et al.*('173) in view of Beck *et al.* ('963) because, Wright *et al.*('173) in view of Beck *et al.* ('963) teach molding and ejecting a plurality of plastic containers whereas Porfano *et al.* ('044) teach a process for assembling and packaging a plurality of containers (col. 4, lines 50-60).

Further regarding claims 20 and 26 and in regard to claims 21–25 and 27-30, McGahhey ('489) teach a method for sealing a plurality of vials including clamping said vials in a heater having a first arm and a second arm (32, 44), applying heat to seal said vials by measuring a heating time (see col. 1, lines 32-42), stopping the heating after a predetermined time has lapsed and unclasping said first arm and a second arm (32, 44) to remove said sealed vials (containers). Therefore, it would have been obvious for one of ordinary skill in the art to have sealed said plurality of vials including clamping said vials in a heater having a first arm and a second arm (32, 44), applying heat to seal said vials by measuring a heating time (see col. 1, lines 32-42), stopping the heating after a predetermined time has lapsed and unclasping said first arm and a second arm (32, 44) to remove said sealed vials (containers) as taught by McGahhey ('489) in the process of Wright *et al.*('173) in view of Beck *et al.* ('963) and in further view of Porfano *et al.* ('044) because, Porfano *et al.* ('044) specifically teach sealing of a plurality of vials, whereas Wright *et al.*('173) in view of Beck *et al.* ('963) teach molding and ejecting a plurality of plastic containers.

Further regarding claims 20 and 26 and in regard to claims 21–25 and 27-30, although McGahhey ('489) teaches measuring the heating time, McGahhey ('489) does not specifically teach measuring the temperature. JP 11-100008 teaches an impulse sealer that measures the sealing temperature and stops the process after the optimum temperature has been reached (see Abstract). Therefore, it would have been obvious for one of ordinary skill in the art to have measured the sealing temperature and stopped the process after the optimum temperature had been reached as taught by JP 11-100008 in the process of Wright *et al.*('173) in view of Beck *et*

al. ('963) and in further view of Porfano *et al.* ('044) and McGahhey ('489) because, Porfano *et al.* ('044) specifically teach sealing of a plurality of vials, whereas Wright *et al.*('173) in view of Beck *et al.* ('963) teach molding and ejecting a plurality of plastic containers and also because, JP 11-100008 specifically teaches that temperature control provides for improved process control and hence an improved product.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stefan Staicovici, Ph.D. whose telephone number is (571) 272-1208. The examiner can normally be reached on Monday-Friday 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Colaianni, can be reached on (571) 272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stefan Staicovici, PhD

Primary Examiner 3/19/05

AU 1732

March 19, 2005